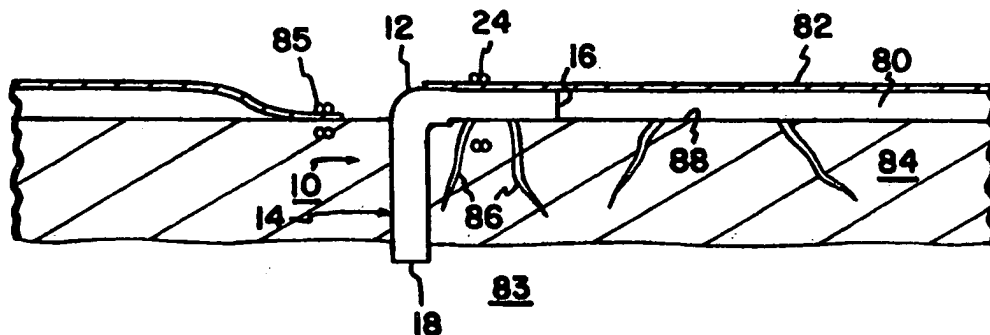




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 2/06	A1	(11) International Publication Number: WO 99/36000 (43) International Publication Date: 22 July 1999 (22.07.99)
(21) International Application Number: PCT/US98/27505 (22) International Filing Date: 22 December 1998 (22.12.98) (30) Priority Data: 09/009,674 20 January 1998 (20.01.98) US (71) Applicant: HEARTSTENT CORPORATION [US/US]; 651 Campus Drive, St. Paul, MN 55112 (US). (72) Inventors: TWEDEN, Katherine, S.; 1175 Ashley Lane, Mahtomedi, MN 55115 (US). CONRAD, Timothy, R.; 11068 Branching Horn, Eden Prairie, MN 55347 (US). (74) Agent: BRUESS, Steven, C.; Merchant, Gould, Smith, Edell, Welter & Schmidt, P.A., 3100 Norwest Center, 90 South Seventh Street, Minneapolis, MN 55402-4131 (US).		(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: TRANSMYOCARDIAL IMPLANT WITH SEPTAL PERFUSION



(57) Abstract

A transmymocardial implant includes a hollow rigid conduit having a first portion and a second portion. The first portion is sized to be received within a coronary vessel lumen. The first portion has an axial dimension aligned with an axis of the vessel. The second portion is sized to extend from the vessel through a myocardium into a heart chamber. The conduit has open first and second ends on axial ends of respective ones of the first and second portions to define a blood flow pathway within an interior of the conduit between the first and second ends. The first portion has at least one radial opening formed therethrough for blood to flow radially outward of the first portion proximally to the first end.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

TRANSMYOCARDIAL IMPLANT WITH SEPTAL PERFUSION**BACKGROUND OF THE INVENTION**5 1. **Field of the Invention**

This invention pertains to an implant for passing blood flow directly between a chamber of the heart and a coronary vessel. More particularly, this invention pertains to such an implant with an enhance design for providing blood flow to septal perfusing and branching arteries.

10 2. **Description of the Prior Art**

Commonly assigned and co-pending U.S. Patent Application Serial No. 08/882,397 filed June 25, 1997, entitled "Method and Apparatus for Performing Coronary Bypass Surgery", and filed in the name of inventors Mark B. Knudson and William L. Giese, teaches an implant for defining a blood flow conduit directly from
15 a chamber of the heart to a lumen of a coronary vessel. An embodiment disclosed in the aforementioned application teaches an L-shaped implant in the form of a rigid conduit having one leg sized to be received within a lumen of a coronary artery and a second leg sized to pass through the myocardium and extend into the left ventricle of the heart. As disclosed in the above-referenced application, the conduit is rigid
20 and remains open for blood flow to pass through the conduit during both systole and diastole. The conduit penetrates into the left ventricle in order to prevent tissue growth and occlusions over an opening of the conduit.

Commonly assigned and co-pending U.S. patent application Serial No. 08/944,313 filed October 6, 1997, entitled "Transmyocardial Implant", and filed in
25 the name of inventors Katherine S. Tweden, Guy P. Vanney and Thomas L. Odland, teaches an implant such as that shown in the aforementioned '397 application with an enhanced fixation structure. The enhanced fixation structure includes a fabric surrounding at least a portion of the conduit to facilitate tissue growth on the exterior of the implant.

30 Implants such as those shown in the aforementioned applications include a portion to be placed within a coronary vessel and a portion to be placed within the myocardium. When placing a portion of the implant in the coronary vessel, the

vessel is axially incised a length sufficient to insert the implant. When placed within the coronary vessel, the implant discharges flow axially into the vessel. The vessel may have multiple branching vessels. For example, in the case of a coronary artery, numerous septal perfusing arteries may branch off of the coronary artery to provide blood to the septal wall. The septal perfusing arteries branch off of the floor of the coronary artery. In addition to these, additional small arteries may branch off of the sides of the coronary artery. Due to the axial length of the implant within the vessel, the wall of the implant may block blood flow to these branching arteries resulting in localized ischemia.

10

SUMMARY OF THE INVENTION

According to a preferred embodiment of the present invention, a transmyocardial implant is disclosed for establishing a blood flow path through a myocardium between a heart chamber and a lumen of a coronary vessel residing on an exterior of the heart. The implant includes a hollow rigid conduit having a first portion and a second portion. The first portion is sized to be received within the lumen. The first portion has an axial dimension aligned with an axis of the vessel. The second portion is sized to extend from the vessel through the myocardium into the heart chamber. The conduit has open first and second ends on axial ends of respective ones of the first and second portions to define a blood flow pathway within an interior of the conduit between the first and second ends. The first portion has at least one radial opening formed therethrough for blood to flow radially outward of the first portion proximally to the first end.

15
20

BRIEF DESCRIPTION OF THE DRAWINGS

25

FIG. 1 is a front, top and left-side perspective view of a first embodiment of an implant according to the present invention;

FIG. 2 is a front elevation view of the implant of FIG. 1;

FIG. 3 is a bottom plan view of the implant of FIG. 1;

FIG. 4 is a side elevation view of a second embodiment of an implant according to the present invention;

30

FIG. 5 is a top plan view of the implant of FIG. 4;
FIG. 6 is a bottom plan view of the implant of FIG. 1; and
FIG. 7 is a view of the implant of FIG. 1 in place following surgical placement.

5

DESCRIPTION OF THE PREFERRED EMBODIMENT

With initial reference to FIG. 1, a conduit 10 is shown in the form of an L-shaped rigid tube. The conduit 10 may be formed of titanium or other rigid biocompatible material such as pyrolytic carbon or may be titanium which is coated with pyrolytic carbon. The material of the conduit 10 is preferably a rigid material in order to withstand contraction forces of the myocardium. By way of example, the tube will have an outside diameter D_o of about 3 millimeters and an internal diameter D_i of about 2 millimeters to provide a wall thickness of about .5 millimeters.

15 The tube 10 has a first portion (or vessel end) 12 which is sized to be received within the lumen of a coronary vessel such as the lumen 80 of a coronary artery 82 illustrated in FIG. 7. The conduit 10 has a second portion (or myocardium end) 14 which extends at a right angle to the axis of portion 12. The second portion 14 is sized to extend from the coronary artery 82 directly through the myocardium 84 and protrude into the left ventricle 86 of a patient's heart. The second portion 14 is sized to have a length sufficient for the portion 14 to protrude into the left ventricle 83.

The vessel end 12 has a first opening 16. The myocardium end 14 has a second opening 18 in communication with an interior 20 of the implant 10. Therefore, blood can freely flow through the implant 10 between the left ventricle 83 and the lumen 80 of the coronary artery 82. Blood flows axially out of opening 16 parallel with the axis of lumen 80.

As discussed more fully in the afore-mentioned commonly assigned and co-pending U.S. Patent Application Serial No. 08/882,397, the portion 14 may be provided with tissue-growth inducing material (not shown in the present application) to immobilize the implant 10 within the myocardium 84.

30

The implant 10 includes a radial opening 22 on the vessel portion 12 to permit blood to flow radially outwardly from the vessel portion 12 (relative to the longitudinal axis X – X of vessel portion 12). In the embodiment of FIGS. 1 – 3, the opening 22 is formed by removing the floor of the vessel portion 12 (i.e., that
5 portion of the vessel portion 12 opposing myocardial portion 14). As a result of forming opening 22, septal perfusing arteries may be provided with blood. This is best illustrated in FIG. 7 showing the implant 10 in place. In FIG. 7, the vessel portion 12 is shown residing within a coronary vessel (such as coronary artery 82). The longitudinal axis of the vessel portion is aligned with the axis of the lumen 80.
10 Sutures 24 secure the artery 82 to the vessel portion 12. The proximal portion of the coronary artery is ligated by sutures 85. As shown in FIG. 7, the coronary artery 82 has numerous branching arteries including septal perfusing arteries 86 extending from the floor 88 of the coronary artery 82. With a solid cylindrical vessel portion 12, the arteries 86 within the axial length of the vessel portion 12 will be blocked
15 and deprived of blood. As a result, tissue perfused by these arteries 86 may become ischemic. The opening 22 permits blood to flow radially out of the vessel portion 12 and supply oxygenated blood to these arteries 86.

FIGS. 4 – 6 illustrate an alternative embodiment implant 10' (all similar elements numbered identically with the addition of an apostrophe). Unlike the
20 embodiment of implant 10 where the opening 22 is formed by removing the base of the vessel portion 12, the implant 10' is provided with a plurality of holes 22' perforating the vessel portion 12' to permit flow radially out of the vessel portion 12'. The holes 22' extend the axially length of the vessel portion 12' and surround the cylindrical wall of the vessel portion 12'. In addition to supplying blood to
25 septal perfusing arteries 86 extending from the floor 88 of the artery 82, the holes 22' supply blood to branching arteries (not shown) which may extend from the sides of the coronary artery 82.

In addition to the open base 22 and holes 22', openings through the vessel portion 12 can be formed in other ways. For example, the vessel portion 12 can be
30 formed of cross-hatched material (similar to stent construction) with areas between the material of the portion 12 defining the openings through the vessel portion 12.

While not a preferred embodiment, the myocardial portion 14 may be provided with holes to permit radial flow directly into the myocardium 84. This is consistent with well-known transmyocardial revascularization techniques attempting to supply blood to the myocardium directly by forming holes through the myocardium in communication with the left ventricle. However, such a design is not preferred since the myocardium 84 is thrombogenic and such holes may result in thrombus occluding the implant 10, 10'.

Having disclosed the present invention in a preferred embodiment, it will be appreciated that modifications and equivalents may occur to one of ordinary skill in the art having the benefits of the teachings of the present invention. It is intended that such modifications shall be included within the scope of the claims which are appended hereto.

WHAT IS CLAIMED:

1. A transmyocardial implant for establishing a blood flow path through a myocardium between a heart chamber and a lumen of a coronary vessel residing
5 on an exterior of said wall, said implant comprising:
a hollow rigid conduit having a first portion and a second portion;
said first portion sized to be received within said lumen, said first
portion having an axial dimension aligned with an axis of said vessel;
said second portion sized to extend from said vessel through said
10 myocardium into said chamber;
said conduit having open first and second ends on axial ends of
respective ones of said first and second portions to define a blood flow
pathway within an interior of said conduit between said first and second
ends; and
15 said first portion having at least one radial opening formed
therethrough for blood to flow radially outward of said first portion
proximally to said first end.
2. A transmyocardial implant according to claim 1 wherein said first portion is
20 perforated.
3. A transmyocardial implant according to claim 1 wherein said first portion and
second portion are disposed at an angle relative to one another and with said first
portion having a base opposing said second portion, said base being substantially
25 open for blood to flow through said base in addition to flowing axially out of
said first open end.
4. A transmyocardial implant according to claim 1 wherein the second portion is
solid to block radial flow from said second portion.
30
5. A transmyocardial implant according to claim 1 wherein the first portion is an
expandable stent.

FIG. 1

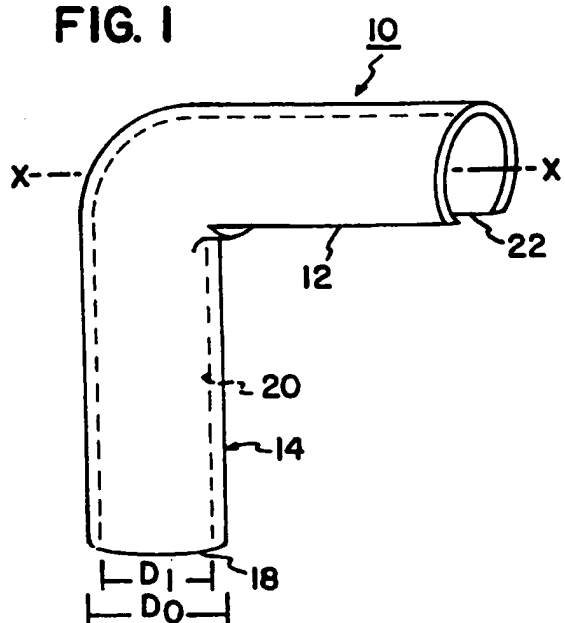


FIG. 2

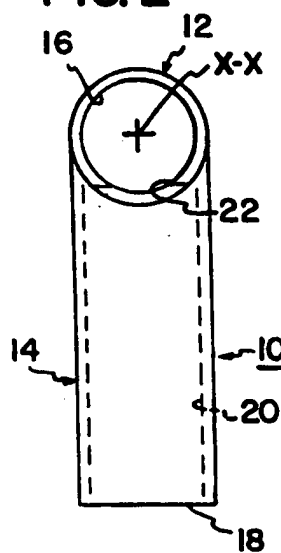


FIG. 3

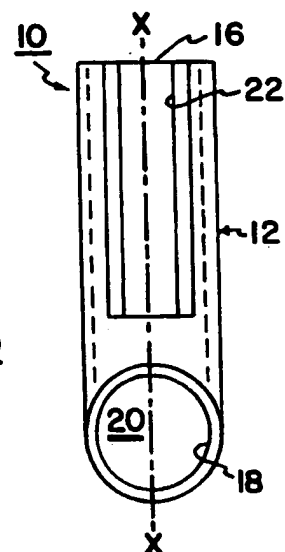


FIG. 4

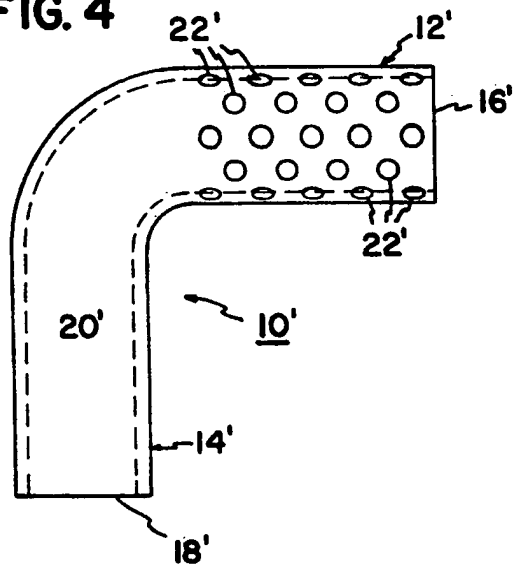


FIG. 5

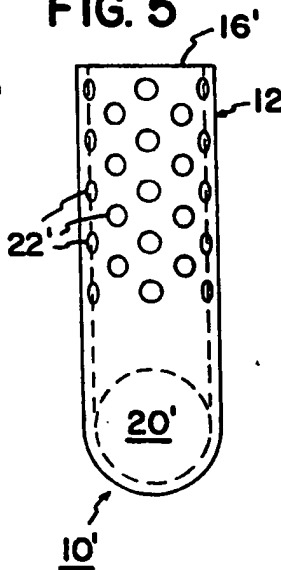


FIG. 6

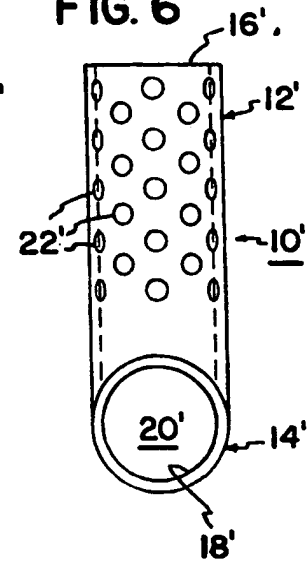
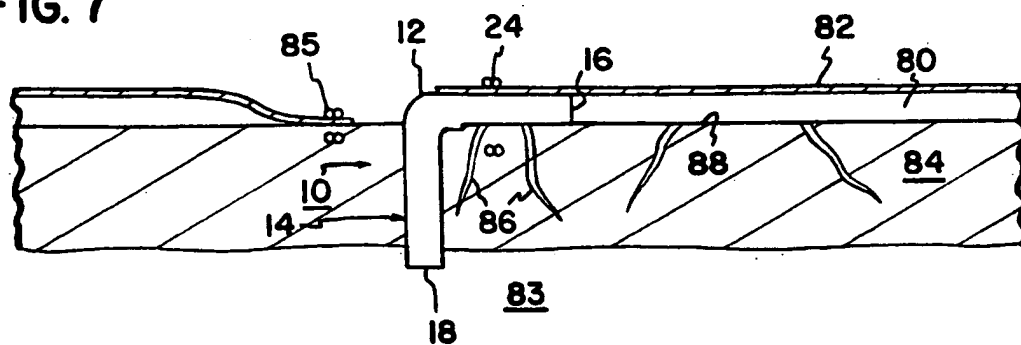


FIG. 7



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/27505

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 429 144 A (WILK) 4 July 1995 see the whole document -----	1
A	MASSIMO ET AL: "Myocardial revascularisation by a new method of carrying blood directly from the left ventricular cavity into the coronary circulation." JOURNAL OF THORACIC SURGERY, vol. 34, 1 August 1957, pages 257-264, XP002103311 see figure 2 -----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

20 May 1999

Date of mailing of the international search report

01/06/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Smith, C

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/27505

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5429144 A	04-07-1995	US 5409019 A	25-04-1995
		US 5287861 A	22-02-1995
